UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND and IRONWORKERS LOCAL 383 HEALTH CARE PLAN, individually and on behalf of all those similarly situated,

Plaintiffs,

-against-

ALLERGAN, INC.,

Defendant.

Civil Action No. 18-00816

CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND

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Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") and Plaintiff Ironworkers Local 383 Health Care Plan ("Ironworkers"), on behalf of themselves and all others similarly situated, file this civil antitrust action for injunctive relief for violations of Sections 1 and 2 of the Sherman Act, and under applicable state laws for damages, against Defendant ALLERGAN, INC. ("Allergan" or "Defendant"), for Allergan's unlawful monopolization of the market for prescription Restasis (cyclosporine ophthalmic emulsion) sales in the United States. Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiffs specifically allege:

I. INTRODUCTION

1. This case challenges a monopolist's willful and wide-ranging scheme to preserve and extend its position by hook or by crook. That monopolist is Allergan, a large pharmaceutical corporation and maker of the blockbuster drug Restasis.

2. Restasis is a frequently prescribed dry-eye disease ("DED") treatment that, throughout the relevant period, has been the only cyclosporine ophthalmic emulsion ("cyclosporine") treatment available in the United States. In 2016, Allergan's total Restasis sales in the United States alone were approximately $1.5 billion—accounting for over 10% of Allergan's reported 2016 revenue.

3. Restasis originated from U.S. Patent No. 5,474,979 (the "Ding I patent") and related U.S. Patent Nos. 4,839,342, 4,649,047, and 5,981,607 (together, Ding I and "related patents"), all of which were issued in or before 1995 and which expired no later than May 17, 2014. During that 20-year period, Allergan enjoyed billions of dollars in Restasis sales.

4. Allergan unlawfully extended its Restasis monopoly beyond the May 17, 2014

expiration of Ding I and related patents through a multifaceted overarching anticompetitive scheme to delay, restrain, or otherwise foreclose any would-be generic competition to Restasis. Allergan's scheme included at least the following deliberate and anticompetitive acts:

i. Allergan's fraudulently inducing the United States Patent and Trademark Office ("PTO") to issue, starting in January 2014, a second wave of Restasis patents (the "Second Life Patents") with ostensible expiration dates in or after 2024, all of which were *ab initio* invalid as obvious in light of Ding I and other prior art and should not and would not have been granted but for Allergan's fraudulent conduct;

ii. Allergan's wrongful submission of the Second Life Patents for listing in the U.S. Food and Drug Administration's ("FDA's") Orange Book, when Allergan knew they were invalid and that their listing would require numerous would-be generic manufacturers to provide "paragraph IV" certifications with any Abbreviated New Drug Applications ("ANDA") submitted to the FDA, thereby enabling Allergan to initiate patent-infringement litigation that would in turn trigger the automatic stay of FDA approval of those ANDAs for up to 30 months;

iii. Allergan's institution of sham litigation against ANDA filers based on patents it knew were invalid and thus unenforceable, the purpose of which was to delay FDA approval of any ANDAs to produce generic cyclosporine regardless of the actual merits of such litigation;

iv. Allergan's serial submission to the FDA of sham citizen and other petitions, the purpose and intent of which was to—and in fact did—delay the FDA's approval process for all pending ANDAs to produce generic cyclosporine; and

v. Allergan's September 2017 anticompetitive, sham ownership transfer and

licensing agreement (the "Agreement") with the Saint Regis Mohawk Tribe (the "Tribe")—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind—whereby Allergan transferred the Second Life Patents to the Tribe and then licensed them back, with the express intent of relying on the Tribe's sovereign immunity to avoid the invalidation of the Second Life Patents by the Patent Trial and Appeal Board ("PTAB"). Indeed, this most recent move has spurred a Congressional investigation into its propriety.[1]

5. Allergan implemented this scheme with the intent to use government processes to impair or otherwise foreclose generic competition and thereby maintain its Restasis monopoly. Allergan's unlawful conduct deprived Plaintiffs and other indirect purchasers of Restasis of the benefits of effective generic competition from May 17, 2014 (the day the Ding I and related patents expired) through at least the present day. This suit is brought on behalf of Plaintiff UFCW and Plaintiff Ironworkers and two proposed Classes of indirect purchasers (also known as "end payors") of Restasis that, as a result of Allergan's scheme, were forced to pay supracompetitive prices for all of the Restasis purchased indirectly from Allergan after May 17, 2014 (when, but for Allegan's scheme, less-expensive generic Restasis products would have otherwise been available in the marketplace). This suit seeks to hold Allergan accountable for its manipulation of the PTO, the FDA, and the federal judiciary in violation of the antitrust laws, and the resultant damages to Plaintiffs and other Class members.

II. JURISDICTION AND VENUE

6. Plaintiffs bring this Action under Section 16 of the Clayton Act (15 U.S.C. § 26) for injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendant for

[1] Michael Erman, U.S. House committee launches probe of Allergan patent deal, Reuters, Oct. 3, 2017, https://www.reuters.com/article/us-allergan-patents/u-s-house-committee-launches-probe-of-allergan-patent-deal-idUSKCN1C8262 (last visited Jan.18, 2018).

the injuries sustained by Plaintiffs and the members of the Classes described herein by reason of the violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2).

7. This Action is also instituted under the antitrust, consumer protection, and common laws of various states and territories for damages and equitable relief, as described below.

8. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and Section 16 of the Clayton Act (15 U.S.C. § 26). In addition, jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1332(d) and 1367.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a), (b), (c), and (d), and 15 U.S.C. §§ 15(a), 22. During the Class Period (defined below), Allergan resided, transacted business, was found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District. Significantly, Allergan maintained and continues to maintain significant offices and operations within 30 miles of this Court's Brooklyn courthouse, including its "US Administrative Headquarters" in Parsippany, New Jersey and its U.S. sales operations offices in Jersey City, New Jersey.

10. Allergan's conduct, as described in this Complaint, was within the flow of, was intended to have a substantial effect on, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

11. During the Class Period, Allergan manufactured, sold, and shipped Restasis in a continuous and uninterrupted flow of interstate commerce, which included sales of Restasis in this District, advertisement of Restasis in media in this District, monitoring prescriptions of Restasis by prescribers within this District, and employment of product detailers in this District,

who as agents of Allergan marketed Restasis to prescribers in this District. Allergan's conduct had and continues to have a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this District.

12. This Court has personal jurisdiction over Allergan. Allergan has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

13. Plaintiff UFCW is an employee welfare benefit plan. UFCW's office—from which it pays health and prescription drug benefits—is located in Cook County, Illinois. During the Class Period, UFCW purchased, paid for, and/or provided reimbursement for Restasis in Illinois. UFCW paid more than it would have absent Allergan's unlawful scheme to prevent generic entry. UFCW will continue to purchase, pay for, and/or provide reimbursement for Restasis and/or any generic equivalent and sustain injury unless the unlawful conduct alleged herein is enjoined.

14. Plaintiff Ironworkers is a self-funded, multi-employer health and welfare plan governed by ERISA. The Plan is administered by Benefit Plan Administration of Wisconsin, whose offices are at 2901 W. Beltline Highway, Suite 100, Madison, WI 57313-4226. During the Class Period, Ironworkers purchased, paid for, and/or provided reimbursement for Restasis in Wisconsin. Ironworkers paid more than it would have absent Allergan's unlawful scheme to prevent generic entry. Ironworkers will continue to purchase, pay for, and/or provide reimbursement for Restasis and/or any generic equivalent and sustain injury unless the unlawful

conduct alleged herein is enjoined.

15. Defendant Allergan, Inc. is a corporation organized under Delaware law with its principal place of business located in Irvine, California. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark. Allergan also was the applicant for and holder of each of the six Second Life Patents Allergan claimed cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014); U.S. Patent No. 8,648,048 (dated Feb. 11, 2014); U.S. Patent No. 8,685,930 (dated Apr. 1, 2014); and US 9,248,191 (dated Feb. 2, 2016).

16. As of September 8, 2017, Allergan purports to have transferred its ownership interests in the Second Life Patents to the Tribe. The Saint Regis Mohawk Reservation, Akwesasne, spans portions of New York State in the United States and Ontario and Quebec Provinces in Canada.

17. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and/or with Allergan's actual, apparent, and/or ostensible authority.

IV. CONTINUING VIOLATIONS

18. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Allergan's unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs and the members of the Damages Class can recover for damages they suffered during any applicable limitations

period.

V. CLASS ACTION ALLEGATIONS

19. Plaintiffs, on behalf of themselves and all other similarly situated indirect purchasers, seek damages, measured as overcharges, trebled where available under applicable law, against Allergan based on allegations of anticompetitive conduct in the market for Restasis and its generic equivalents.

20. Plaintiffs bring this Action on behalf of themselves and as a class action under Federal Rules of Civil Procedure 23(a) and (b)(2), seeking equitable and injunctive relief on behalf of a Class of indirect purchasers (the "Nationwide Injunctive Relief Class") defined as follows:

> All persons and entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Restasis, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, from May 17, 2014 through and until the anticompetitive effects of Allergan's conduct cease (the "Nationwide Injunctive Relief Class Period").
>
> This class excludes: (a) Allergan, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Restasis only for purposes of resale or directly from Allergan; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) pharmacy benefit managers; and (f) any judges or justices involved in this Action and any members of their immediate families.

21. Plaintiffs also bring this Action on behalf of themselves and as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3) seeking damages pursuant to the antitrust, unfair competition, and consumer protection laws of the states and territories listed below (the "End-Payer Damages Jurisdictions") on behalf of the following class (the "Damages Class"):

> All persons and entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Restasis in Arizona, Arkansas, California, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, and Wisconsin, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, from May 17, 2014 through and until the anticompetitive effects of Allergan's conduct cease (the "Damages Class Period").
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> This class excludes: (a) Allergan, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Restasis for purposes of resale or directly from Allergan; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) pharmacy benefit managers; and (f) any judges or justices involved in this action and any members of their immediate families.

22. The Nationwide Injunctive Relief Class and the Damages Class are referred to herein as the "Classes." The Nationwide Injunctive Relief Class Period and the Damages Class Period are referred to herein as the "Class Period."

23. Although Plaintiffs do not know the exact number of the members of the Classes, they believe there are thousands of members in each Class.

24. Common questions of law and fact exist as to all members of the Classes. This is particularly true given the nature of Allergan's scheme, which did not vary as to class members individually, but applied equally to all Class members, thereby making appropriate relief with respect to the Classes as a whole. Such questions of law and fact common to the Classes include, but are not limited to:

a. whether Allergan willfully obtained and/or maintained monopoly power over Restasis and its generic equivalents;

b. whether Allergan obtained the Second Life Patents by fraud;

c. whether Allergan unlawfully excluded competitors from the market for Restasis and its generic equivalents;

d. whether Allergan unlawfully delayed or prevented generic manufacturers of cyclosporine ophthalmic emulsion from entering the market in the United States;

e. whether Allergan maintained monopoly power;

f. whether Allergan entered into an illegal contract, combination, conspiracy and/or other agreement in restraint of trade through its agreement with the Tribe;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

h. whether Allergan's activities as alleged herein have substantially affected interstate commerce;

i. whether, and if so to what extent, Allergan's conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and Class Members;

j. Whether the alleged scheme violated the Sherman Act as alleged in Counts One through Four herein;

k. Whether the alleged conduct violated state laws, as alleged in Counts Five and Six herein;

l. Whether the conduct of Allergan, as alleged in this Complaint, caused injury to the business or property of Plaintiffs and the members of the Classes;

m. The effect of Allergan's alleged conduct on the prices of cyclosporine ophthalmic emulsion products sold in the United States during the Class Period;

n. The appropriate injunctive and related equitable relief for the Nationwide Injunctive Relief Class; and

o. The appropriate class-wide measure of damages for the Damages Class.

25. The questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members.

26. Plaintiffs' claims are typical of the claims of Class members. Plaintiffs and all members of the Classes are similarly affected by Allergan's wrongful conduct in that they paid artificially inflated prices for Restasis purchased indirectly from Allergan and were deprived of earlier and more robust competition from less-expensive generic cyclosporine ophthalmic emulsion products as a result of Allergan's wrongful conduct. Plaintiffs' claims arise out of the same common course of conduct giving rise to the claims of the other members of the Classes.

27. Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs are members of each Class, and their interests are coincident with, and not antagonistic to, those of the other members of the Classes. Plaintiffs are represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.

28. Class action treatment is a superior method for the fair and efficient adjudication of the controversy because, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

29. The prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications, establishing incompatible standards of

conduct for Allergan.

VI. REGULATORY BACKGROUND

30. Branded drug companies can, and do, obtain valid patents from the PTO that cover new prescription drug products. Such patents, awarded on the basis of an applicant's candor and good faith regarding the genuineness of the invention claimed, encourage discovery and development of new medicines, providing—as a reward for true ingenuity—protection from competition by other drug companies for a length of time set statutorily by Congress.

31. Once the lawful periods of patent exclusivity expire on branded drug products, would-be competitors can seek FDA approval to sell generic versions of the branded drug, allowing those companies to manufacture generic products that are just as safe and effective, but far less expensive. With generic competition, the medication becomes affordable.

32. Thus, branded drug companies have a statutory period of time to charge high prices for medications that, in fact, cost little to manufacture; but it is a limited period, after which would-be competitors may enter the market with lower-cost substitutes. And the timing of approval of these competing products depends on, among other things, the truthfulness of the patent information the brand provides to the FDA.

33. Under the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392, manufacturers who create a new branded drug product must obtain FDA approval to sell it by filing a New Drug Application ("NDA") with the agency. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on patents applicable to that drug. *Id.* § 355(a), (b). The FDA must rely, completely, on the information provided by the manufacturer and list those patents publicly, so that would-be generic competitors understand the scope of the brand's ostensible patent protection.

34. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the Hatch-Waxman Amendments, in an effort to streamline FDA processes and facilitate competition while incentivizing pharmaceutical manufacturers to innovate. Under the Hatch-Waxman Amendments, competitors wishing to sell a generic equivalent of a branded drug must file an ANDA, an abbreviated application that relies in substantial part on the scientific finding of safety and effectiveness included by the branded drug manufacturer in its NDA. 21 U.S.C. § 355(j).

35. Generic manufacturers must wait until the expiration of all listed patents, unless they can certify that their generic product does not infringe the listed patents or that such patents are invalid. Such a certification may permit the brand company to sue for patent infringement—but a brand company may do so only if it has an objectively reasonable basis to claim the patent's protection. The listed patents, would-be competitors' certifications, and brand company's infringement suits all affect the timing of FDA approval of generic equivalents.

36. As a further guard against error in the patent-prosecution process that may result in improvidently issued patents, Congress recently established an "*inter partes* review" ("IPR") process that empowers the PTAB to review the validity of a previously issued patent. If the PTAB determines a challenger has a reasonable likelihood of prevailing on at least one of the challenged claims, it may conduct a trial on the claims' validity in which the patent holder is the defendant.

37. This framework produces several basic rules. First, companies seeking to sell a branded drug may only pursue valid patents, with candor and forthrightness in dealing with the PTO. Second, branded drug companies cannot provide false or misleading patent or other drug

information to the FDA and wield that information to delay entry of less-expensive generic medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Third, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success of the merits; the mere filing of such a lawsuit stalls legitimate efforts to gain market entry. Fourth, federal policy favors prompt invalidation of improvidently issued patents; patent holders cannot knowingly wield invalid patents to thwart competition.

38. Allergan broke all of these basic rules.

A. The Benefits of Generic Drug Competition to the Class

39. Under the terms of the FDCA and the Hatch-Waxman Amendments, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the branded drug. 21 U.S.C. § 355(j)(2)(A)(iv). Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. *Id.* § 355(j)(8). For drugs not intended to be absorbed into the bloodstream, including Restasis, the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed [*i.e.*, branded] drug in safety and therapeutic effect." *Id.*; 21 C.F.R. § 320.24(b)(6). Drugs that meet bioequivalence requirements through an FDA-approved method will be rated "AB," indicating they are therapeutically equivalent to other drugs with the same rating in the same category.

40. Because generic versions of a corresponding branded drug product are clinically identical commodities that cannot be differentiated, the primary basis for generic competition is

price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

41. Since the passage of the Hatch-Waxman Amendments to the FDCA, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded drug prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create an economic dynamic in which the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the branded drug manufacturer, but dramatic savings for the American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding branded drug sales and (with multiple generics on the market) prices had dropped 85%. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010). According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics. As a result, brand name drug companies, such as Allergan, view competition from generic drugs as a grave threat to their bottom lines.

42. Generic competition enables Plaintiffs and all members of the proposed Classes

to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the branded drug at a reduced price.

43. Until a generic version of the branded drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the branded drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Branded drug manufacturers, such as Allergan, are well aware of generics' rapid erosion of their brand sales. Branded drug manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

1. Prices drop upon entry of the first AB-rated generic

44. Experience and economic research show that the first generic manufacturer to enter the market prices its product below the price of its branded counterpart. Every state either requires or permits a prescription written for the branded drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

2. Prices plummet when additional AB-rated generics enter the market

45. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

46. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates indicate that a single generic launch results in a near term retail price reduction of at least 10%, but that with two generic entrants

near term retail price reduction is about 50%. *See, e.g.*, Luke M. Olson & Brett W. Wendling, The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period, FTC Working Paper No. 317 (2013).

47. Soon after generic competition enters the market, the vast majority of the sales formerly enjoyed by the brand shift to the generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry.

B. Patent Protection for Branded Drugs

1. Patent portfolios for blockbuster drugs

48. There is a predictable pattern to the way a branded drug company will develop its patent portfolios for a blockbuster drug. The first group of patents in the portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

49. After filing applications for the original patents, the company continues its research and development efforts with hopes of developing a drug product that eventually could be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drug only if the branded drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. Often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the

number of patent filings for the drug grows, so does the volume of prior art beyond which the branded drug company must show non-obvious distinctions.

50. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and—if valid and enforceable—may prove impossible for generic manufacturers to design around while meeting the FDA's bioequivalence criteria. While generic versions of the brand product may be able to obtain FDA approval and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the branded drug company has no lawful means of trying to prevent competitors from entering the market.

51. Therefore, a typical patent portfolio for a branded drug has its most significant patents issuing first; over time, the later-issued patents generally become increasingly narrow and more difficult to obtain. Even if the branded drug manufacturer obtains that narrower coverage, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics, thus preventing the branded drug company from satisfying its burden of proving infringement to keep generics out of the market.

2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties designed to protect the public interest in the PTO's issuance of valid and lawfully obtained patents

52. Because patents often enable a branded-product manufacturer to exclude competition and charge supracompetitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

53. Patent prosecutions are non-adversarial. Thus, in order to help assure that the "public interest is best served" though the PTO's issuance of patents that are valid and lawfully obtained, patent applications are subject to various special oaths and duties. Among these various

special oaths and duties is the Duty of Disclosure, Candor, and Good Faith, which requires the applicant to disclose to the PTO of "all information known . . . to be material to patentability" including with respect to prior art. *See* 37 C.F.R. § 1.56. And this duty extends not only to each and every named inventor on the patent application but to each and every "attorney or agent who prepares or prosecutes the application" as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* § 1.56(c). Where fraud on the PTO "was practiced or attempted" or the Duty of Disclosure, Candor, and Good Faith "was violated through bad faith or intentional misconduct," no patent should be granted. *Id.* § 1.56(a).

C. New Drug Applications (NDAs) and Patent Listings in the FDA's Orange Book

54. Under the FDCA, drug companies that wish to sell a new drug product must file with the FDA an NDA. That application must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355 (a), (b).

55. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents it believes cover its drug products. The FDA then publishes a list of those patents in the publicly available *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the branded drug. 21 C.F.R. § 314.53(c)(2)(ii).

56. The brand name drug manufacturer can submit its patents for Orange Book listing by filing with the FDA a Form 3542. *Id.* § 314.53(c)(1). Under the FDA rules, the branded manufacturer is only permitted to list patents that are reasonably enforceable. Form 3542

expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (*i.e.*, a situation where there are no patents that could be reasonably asserted in an infringement lawsuit). Form 3542 likewise requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent claiming the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

57. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the authority or resources to verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book–listed patents.

D. Abbreviated New Drug Applications (ANDAs), Orange Book-Related Generic Manufacturer Certifications, and Related Litigation

58. The 1984 Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting a generic manufacturer to file an ANDA with the FDA that may rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the blood stream at a similar rate over a similar period of time, are expected to be equally safe and effective.

59. At the same time, the Hatch-Waxman Amendments sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other

things, permitting a branded drug company to file a patent infringement lawsuit in good faith against a generic before the generic actually brought its product to market.

60. The Hatch-Waxman Amendments substantially achieved both goals, advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2016, total prescription drug revenue had soared to over $450 billion, with generic drugs accounting for 89% of total prescriptions.

1. The Hatch-Waxman Amendments provide for an automatic 30-month stay of FDA ANDA approvals to resolve legitimate patent-infringement claims

61. The Hatch-Waxman Amendments created a procedural mechanism to resolve patent disputes between manufacturers of branded and generic drugs before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Amendments permitted a branded drug manufacturer to sue a generic for patent infringement even if their products had not launched yet.

62. Once one or more patents are listed in the Orange Book as pertaining to the branded drug, a generic manufacturer seeking FDA approval of a generic equivalent must certify that the generic drug addressed in its ANDA will not infringe any of those patents. A generic manufacturer can make one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA;

ii. that the patent for the brand name drug has expired;

iii. that the patent for the brand name drug will expire on a particular date

and the generic company does not seek to market its generic product before that date; or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product. 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

63. If a generic manufacturer files a certification based on the last of these options (a "paragraph IV" certification), the owner of the patent—generally the branded drug manufacturer—can sue the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *Id.* §§ 355(c)(3)(C), (j)(5)(B)(iii). Until one of those conditions is met, the FDA cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

64. The branded drug manufacturer may file patent-infringement claims more than 45 days after receiving the paragraph IV certification, but doing so would not trigger the automatic 30-month stay of FDA approval.

2. The Hatch-Waxman Amendments incentivize generic manufacturers to challenge questionable patents before launch by awarding 180-day exclusivity to the first paragraph IV-certified ANDA filer

65. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a paragraph IV certification is eligible for 180 days of market exclusivity. This means that other, secondary ANDA-filers will not be able to launch their own generic products for at least six months after the first generic—known as the "first-filer"—launches its product.

66. During this 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, this 180-day exclusivity period is very valuable and it is often the case that most of a first-filer's profits are earned during this 180-day exclusivity period. *FTC v. Actavis*, 133 S. Ct. 223, 229 (2013).

67. If the only versions of a drug on the market are the branded drug and the first-filer's product, then the first-filer prices its product below the brand product, but not as low as if it were facing competition from other generics. In these circumstances the first-filer's product may compete only with the branded drug, and because the branded drug company rarely drops the branded drug price to match the first-filer's, the first-filer does not face the kind of price competition that arises when additional generic competitors enter the market.

E. The Citizen Petition Process

68. Pharmaceutical companies have multiple avenues and opportunities through which to communicate their views to the FDA. For example, the FDA holds public advisory meetings, which can be requested by pharmaceutical companies, to address issues regarding specific drug products or more generalized issues that pertain to many products. Additionally, there are industry and FDA fora for discussion that permit interaction and debate.

69. Pharmaceutical companies, like members of the public, may file a petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a citizen petition or "FDA Petition." Citizen petitions are intended to convey for the FDA's consideration in terms of its policies and procedures genuine concerns about safety and scientific or legal issues regarding an FDA-regulated product any time before or after market entry.

70. A citizen petition may be filed to request that the FDA take action regarding drug

approval requirements, including those involving generic drugs. To move the FDA to grant this type of request, the petition must include supportive, clinically meaningful data, and the requested relief must be consistent with the FDA's authority and with the Hatch-Waxman Amendments' statutory and regulatory framework.

71. FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days after the date on which the petition was submitted. 21 C.F.R. § 10.30(e)(2). That response may be to approve the request in whole or in part, or to deny it. The Commissioner may also provide a tentative response with a full response to follow.

72. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. A response to a citizen petition and the approval of generic drugs are each considered final FDA actions that can be appealed under the Administrative Procedures Act. A petitioner who does not agree with the FDA's response to a petition can sue the FDA (and many have), and seek to have the FDA's response overruled as arbitrary and capricious. The FDA therefore needs to have a complete administrative record reflecting that its response was based on sound science, in part to defend itself in any subsequent appeal. The FDA also must base its decisions about the fundamental safety and efficacy of drug products on sound science to protect users of those products.

73. These activities strain the FDA's limited resources, and citizen petition reviews can delay FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

74. Indeed, in July 2006, Gary Buehler, R.Ph., former FDA Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Of these 42, only three petitions led to a change in FDA policy on the basis of data or information submitted in the petition.

75. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years, as branded drug companies have sought to compensate for dwindling new-product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for more than a year, long after the branded drug manufacturer received notice of the ANDA filing, and have had the (intended) effect of delaying the approval of generic drugs while the FDA evaluated the citizen petition. One recent empirical study found that "[m]any citizen petitions from competitor companies appear to be last-ditch efforts to hold off generic competition. In fact, the most common grouping of petitions was those filed within six months of generic approval." Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 70 (2017).

76. Delaying generic competition is a lucrative strategy for a branded drug manufacturer. Given the marketplace's preference for generic over branded products, the cost of filing a citizen petition may be trivial compared to the value of securing even a few months of generic entry delay.

77. FDA officials have further acknowledged abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with

respect to the legality or scientific soundness of approving a drug application," and instead "try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

78. It is well known in the pharmaceutical industry that it is FDA practice to withhold ANDA approvals until after its consideration of, and response to, a citizen petition is complete. On this subject, Director Buehler acknowledged that, with respect to the FDA's Center for Drug Evaluation and Research ("CDER"), "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

79. In an effort to deal with the potential anticompetitive abuse of the citizen petition process, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which was enacted on September 27, 2007. Pub. L. No. 110–85, 121 Stat. 823 (2007). The FDAAA adds new section 505(q) to the FDCA. Section 505(q)(1)(A) provides that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A)(ii). The FDAAA did not provide the FDA with additional resources to enable it to more promptly respond to petitions, however. Instead, the FDAAA provides only that the FDA must communicate any ANDA-approval delay within thirty days of its determination that a delay is necessary. Thus, a branded drug manufacturer may still be able to delay generic approval while the FDA considers whether the relevant citizen petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition has any merit. In the high-stakes world of pharmaceuticals, even relatively

short delays can cost generic firms and drug purchasers millions of dollars in lost sales and prescription drug overpayments, respectively.

80. Even after several years of experience under the FDAAA, the FDA continues to express concerns that citizen petitions are being filed for the purpose of delaying ANDA approvals:

> FDA will continue to gain additional experience and monitor trend data in the FY 2012 reporting period to assist Congress in determining whether section 505(q) is accomplishing the stated goals of the legislation. Based on the petitions that FDA has seen to date, however, the agency is concerned that section 505(q) may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive dug products.[2]

81. Independent research has confirmed the FDA's view. One recent study found that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, 21 U.S.C. § 355(q), which are now the type most often employed to oppose generic entry—and the type Allergan filed here. *See Michael A. Carrier & Carl Minniti, Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 332-33, 333 tbl. 4 (2016).

F. Proceedings Before the Patent Trials and Appellate Board (PTAB)

82. In 2011, Congress passed the Leahy-Smith America Invents Act to address a widely held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy. Pub. L. 112–29, 125 Stat. 284 (2011). A centerpiece of the Act was the creation of new IPR proceedings, by which members of the public could challenge improperly issued patents and have them eliminated more quickly and inexpensively than through patent litigation. IPR proceedings also bore the promise of a review by technically educated members of the PTAB who are deeply familiar with the sciences at issue in any

[2] Report to Congress, Fourth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011, Department of Health and Human Services, Food and Drug Administration.

particular proceeding.

83. The Act allows the PTAB to review existing patents and extinguish those rights in an adversarial trial process. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to reconsider the PTO's issuance of a patent and invalidate it on the ground that it was obvious or anticipated by prior art.

84. The PTAB will grant a request for an IPR only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). If it institutes an IPR, the review is conducted before a panel of three technically trained administrative PTAB patent judges.

85. The PTAB must decide the review within one year of the institution date—significantly faster than invalidity issues would generally be adjudicated in a trial before a district court. Notably, the IPR review process can and frequently does take place simultaneously with parallel district-court infringement litigation. The IPR process thus provides a speedy and economical mechanism for an accused patent infringer to challenge a wrongfully issued patent.

86. PTAB trial proceedings have become an exceedingly effective method of challenging improperly granted patents—at least 84% of patents reaching a final written decision in PTAB validity challenges are adjudicated to have at least one invalid claim, and 69% have had *all claims* cancelled as invalid.[3] Given the high likelihood of claim cancellation once an IPR has been instituted, IPR proceedings have earned the moniker "patent death squads," and patent holders are accordingly loathe to being subject to the IPR process.

VII. FACTUAL ALLEGATIONS

A. The FDA Approves Allergan's Restasis

[3] Steve Brachmann & Gene Quinn, *Are more than 90 percent of patents challenged at the PTAB defective*?, June 14, 2017, http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/. (last visited Jan. 18, 2018).

87. Cyclosporine treats DED, also known as keratoconjunctivitis sicca ("KCS"), a painful and irritating condition involving abnormalities and deficiencies in the tear film of the eye. More severe cases of DED can involve or precipitate inflammation with serious potential damage to the ocular surface. Simply put, DED is the failure to produce tears in the normal fashion, in a way that can seriously threaten a patient's eyesight. DED disproportionately afflicts the elderly, menopausal women, and those with systemic diseases such as Sjogren's syndrome, rheumatoid arthritis, lupus, and diabetes.

88. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A,[4] an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is one of the most widely prescribed drugs in the world; last year, in the United States alone sales of Restasis were nearly $1.5 billion.

89. In 1993, Allergan licensed from Sandoz, Inc. the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent

90. No. 4,839,342 issued to Renee Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle, in this case topical administration. The Kaswan patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

91. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine),

[4] Cyclosporin A is sometimes spelled "cyclosporine" to distinguish it from other cyclosporins, such as cyclosporins B, C, and D. *See* U.S. Pat. No. 4,839,342, col. 3, ll. 7-11.

together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "Ding I"), which issued in 1995. Ding I contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. Ding I stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12.

92. The second patent, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method for alleviating dry eye-related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

93. Allergan then began clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (*e.g.*, 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the periodical article Dara Stevenson et al., *Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-severe dry eye disease, and mitigated dry eye disease's effects on vision-related functioning. All

tested concentrations were safe and effective in increasing tearing in certain patient groups.

94. Notably, Stevenson concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and the formulations containing greater amounts of cyclosporine—efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson's study suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

95. Phase 3 trials did just that, with the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000). Phase 3 confirmed the results of Phase 2, and found the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over the patient's baseline, suggesting that it was a contributing factor to the formulations' success.

96. Statistically, there was no significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

97. Following the Phase 3 study, Allergan filed an NDA with the FDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The proposed commercial product, which is Restasis, would contain all of the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the

application in December 2002, authorizing the sale of Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs." Since its launch in 2003, Restasis has been a highly successful product for Allergan.

B. Allergan Prosecutes Serial Patent Applications in an Effort to Obtain Additional Patents to Extend the Restasis Monopoly

1. The PTO repeatedly rejects Allergan's serial efforts to obtain additional patents for "new" combinations of castor oil and cyclosporine that were in fact obvious in light of prior art

98. For over a decade following the FDA's approval of Allergan's Restasis NDA, Allergan filed a variety of patent applications focusing on patenting combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations, with no statistically different outcomes based on the particular combination. Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and, unsurprisingly, the PTO examiner rejected the remaining claims based in part on obviousness in light of Ding I.

99. Allergan then amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis, and, as would be expected, the PTO examiner again rejected the application. Allergan appealed and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177

application"). The '177 application was similar to the '857 application, but it added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

2. In 2009, Allergan concedes that all its "new" cyclosporine/castor oil combination claims are obvious in light of Ding I

100. In June 2009, Allergan contradicted its earlier patentability claims, and admitted with respect to both the '857 and '177 applications that the various composition claims were obvious in light of Ding I. Allergan explained, in writing, that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan, in its own words, "concede[d] that in making this selection (0.05% cyclosporin and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." According to Allergan, the composition claims advanced by the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal.

101. After canceling the previous claims on the '857 application, Allergan tried once more to add to it a new claim regarding another composition of cyclosporine and castor oil. As with all the other composition claims, the PTO examiner rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the '857 application. The '177 application ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

3. Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of new continuation applications, all deriving from the '177 application

102. Having repeatedly failed to convince the PTO to grant patent protection over various "new" composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, in August 2013, Allergan filed six additional continuation applications deriving, directly or indirectly, from the '177 application. These six additional applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As a federal district court invalidating the patents that subsequently issued from these applications later found: "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014." Findings of Fact & Conclusions of Law at 20, *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455 (E.D. Tex. Oct. 16, 2017), ECF No. 523 (hereinafter "Invalidation Decision").

103. In initiating these 2013 applications, Allergan tried to claw back its prior concession that various cyclosporine-castor oil combinations were obvious in light of Ding I, claiming to have new data supporting patentability, based on "unexpected" results showing the claimed Restasis formulation to be particularly effective. The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

104. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists, which, according to Allergan, demonstrated that the Restasis formulations reflected in the 2013 applications outperformed other combinations to a "surprising" extent not anticipated by Ding I and other prior art. Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated "surprising" test

results:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . . . Exhibits E and F also illustrate that the claimed formulations also demonstrated a *4-fold* improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a *4-fold* increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

105. Based on Allergan's representation of Dr. Schiffman's discovery and the declaration itself, the PTO examiner reversed course and allowed the patents to issue with respect to all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and in 2016 as U.S. Patent No. 9,248,191 ("the '191 patent"). These are the Second Life Patents at issue here.

4. Allergan's new 2013 data and unexpected results were neither new nor unexpected, and fraudulently induced the PTO to grant the Second Life Patents

106. In reality, however, the statements and data reflected in Dr. Schiffman's declaration that Allergan cast to the PTO examiner as presenting new and unexpected results were not new. Instead, Dr. Schiffman's declaration consisted of statements plagiarized from an article published in a well-known medical journal thirteen years earlier, Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article"). The Sall Article had relied on Allergan's very own Restasis Phase 3 clinical trial data

that it had recorded in the 1990s. In fact, this was the very periodical that publicized Allergan's Phase 3 clinical results.

107. Not only was the "new" 2013 data not actually new, it did not actually demonstrate unexpected results. As the district court that invalidated the Second Life Patents found:

> [Allergan's] presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

Invalidation Decision at 133 (E.D. Tex. Oct. 16, 2017).

108. In submitting the 2013 continuing applications, Allergan sought new patent protection on substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of prior art. The PTO examiner granted the 2013 claims only upon reliance on Allergan's Shiffman Declaration and Allergan's characterizations of "new" data and surprising results not contemplated by the prior art.

109. Allergan made these representations and characterizations, both by commission and omission, with the intent to deceive the PTO, and such representations and characterizations were material and fraudulently induced the PTO to grant the Second Life Patents. As the district court found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO . . . and the fact that the examiner concluded that unexpected results had been shown . . . the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, *painted a false picture* of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation *created the misleading perception* that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of

> unexpected results to be entitled to no weight, based as it was on evidence that *did not accurately depict* the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

Id. at 82-83 (emphasis added).

110. Had Allergan made clear to the PTO examiner that the Shiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art.

C. Allergan Wrongfully Lists the Invalid Second Life Patents in the Orange Book, Creating Confusion and Delay in the ANDA Approval Process, While Providing a Path to Filing Sham Patent-Infringement Suits Against Would-Be Generic Competitors to Further Delay Generic Entry

111. The Second Life Patents issued beginning on January 14, 2014, starting with the '111 patent, which Allergan immediately submitted for listing in the Orange Book. This listing required any ANDA filer seeking to market generic version of Restasis to file a certification as to that "new" patent.

112. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, the agency had received at least one ANDA for a generic version of Restasis. Up until the listing of the Second Life Patents, ANDAs may have been filed with paragraph II or III certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, just months away. Had Ding I simply expired in May 2014 without Allergan's machinations, any paragraph I- or II-certified ANDAs would have been approved, generic cyclosporine would have been available upon expiration of Ding I, and the competition to Restasis would have created immediate benefits to the Classes in the form of lower prices.

113. Instead, all prior ANDA filers now had to amend their ANDAs to include

paragraph IV certifications with respect to the '111 patent (and eventually the other Second Life Patents). Worse, the confusion Allergan created by its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received any prior ANDA certifications likely was different than the order in which the agency received the paragraph IV certifications with respect to the Second Life Patents, creating various first-filer status uncertainties.[5]

114. The various uncertainties Allergan's actions created—regarding which ANDA filer was eligible for first-filer status and the attendant 180-day exclusivity period—led the FDA on July 28, 2015, to distribute a "Dear ANDA Applicant" letter soliciting the views of all the ANDA filers regarding which ANDA applicant should be deemed the first-filer. Despite the prompt responses the FDA received, including an unsolicited response from Allergan intended to sow still further confusion (discussed below), as of January 2018 the FDA has yet to publically opine on the first-filer issue. Upon information and belief, Allergan's actions effectively chilled the FDA's ANDA approval process pending resolution of the first-filer issue.

115. The wrongful Orange Book listings had another immediate impact: when all ANDA applicants had to file paragraph IV certifications with respect to the Second Life Patents, the inclusion of those certifications enabled Allergan to sue for infringement and trigger the automatic stay of any FDA approval of such ANDA for up to 30 months. In contrast, paragraph II– or III–certified ANDAs are not subject to that automatic 30-month stay of FDA approval.

[5] To the extent Watson Laboratories, Inc. may have been the first-filer, as is suggested by SEC disclosures made by Allergan, Inc., any first-filer uncertainties may have been compounded by Watson's subsequent corporate mergers. Watson Laboratories' parent, Watson Pharmaceuticals, acquired Actavis, Inc. in 2013, and operated thereafter as Actavis, which in 2015 acquired Allergan, and thereafter operated as Allergan. In August 2016, Allergan's Actavis generic business was acquired by Teva, another ANDA applicant that had provided Allergan with notice of its paragraph IV certifications as to the Second Life Patents in July 2015 (but appears to have filed its original ANDA at or near the time of Watson's original ANDA filing in 2011). The extent to which Watson's Restasis ANDA factored into the various mergers as another means to protect the nearly $1.5 billion/year Restasis monopoly is presently unknown.

116. Allergan knew when it listed the Second Life Patents in the Orange Book that such patents were invalid but nevertheless would provide Allergan a basis to delay generic competition to Restasis beyond May 2014 and otherwise would create confusion that would further chill the FDA's ANDA approval process.

D. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I

117. Plaintiffs understand that numerous pharmaceutical manufacturers—including some of the biggest brand and generic pharmaceutical companies in the world—submitted ANDAs seeking the FDA's approval to market generic Restasis. Upon information and belief, but for Allergan's misconduct as alleged herein, one or more of these ANDA filers would have received FDA approval and would have been in a position to supply the commercial quantities of generic Restasis necessary to supply the market upon expiration of Ding I in May 2014. Other ANDA applicants would have been ready at a later date but still within the relevant period.

118. The known manufacturers that have filed ANDAs with the FDA seeking the FDA's approval to market generic Restasis products are identified in the below table:

ANDA Applicant	ANDA No.	When ANDA first submitted, if known	Date Second Life Patent paragraph IV certification made
Watson	203463	Nov. 14, 2011	Jan. 2014
Akorn	204561		July 13, 2015
Mylan	205894		July 20, 2015
Teva	203880		July 23, 2015
Apotex	207606		July 23, 2015
Innopharma (Pfizer subsidiary)	206835		Aug. 3, 2015
Famy Care	208469		Jan. 29, 2016
Twi Pharmaceuticals	209064		June 8, 2016
Deva Holding	209811		Nov. 11, 2016

119. Allergan disputed the sufficiency of Watson's 2011 ANDA application and

related certifications. In the resultant litigation, the court entered a Memorandum Opinion and Order in which it determined that Watson's November 2011 ANDA was not technically received by the FDA, as confirmed by the FDA's responsive August 2013 communication identifying deficiencies needing correction, that, once corrected, would result in a new ANDA filing date. There being no "receipt" by the FDA of the 2011 ANDA, that court concluded, Watson's related certifications were insufficient to trigger the Hatch-Waxman clock. Mem. Op. & Order, *Allergan, Inc. v. Actavis, Inc., et al.*, No. 2:14-cv-00188 (E.D. Tex. Dec. 23, 2014), ECF No. 47.

120. Watson responded to the FDA's letter in October 2013, but as of the court's December 2014 decision, the FDA had not responded to Watson's October 2013 ANDA submissions and related certifications. The status of those Watson October 2013 ANDA submissions remains unclear, but in a May 2014 earnings call Sigurdur Oli Olafsson, then Director and President of Actavis Pharma, confirmed that Watson had "sent in clarifying responses to the questions from the FDA" and that there was "nothing outstanding on us." Actavis reconfirmed in a September 2016 investors' call that there was "no question" that it was still aggressively pursuing the FDA's approval of its Restasis ANDA because it was an important brand product.

121. ANDA application numbers are generally assigned by the FDA in the order in which they are received. Thus, it would appear that Teva's original ANDA application was submitted to the FDA close in time to Watson's 2011 submissions. Allergan has not publically disputed the sufficiency of Teva's pre-July 2015 ANDA submissions and related certifications.

122. Notwithstanding the apparently earlier Watson and Teva original ANDA submissions and certifications, Akorn expressed in a June 2016 investors' call that it believes it is the first-filer. In an August 2016 investors' call, Akorn also confirmed that it had "already

partnered with someone to manufacture the [Restasis generic] product," that the manufacturing partnership had "already been lined up and filed," and that Akorn had already responded to FDA follow-up inquiries and was anticipating "product approval hoping in the near future."

123. Similarly, in an October 2015 earnings call, Mylan's president stated that Mylan remained poised to launch its Restasis generic products upon FDA approval, when he confirmed that Mylan had filed its Restasis ANDA with the FDA "a couple of years back" and was "just waiting to hear from the FDA." In a February 2016 earnings call, Mylan confirmed that it had received the FDA's acceptance of Mylan's ANDA in the middle of 2015.

E. Allergan Files Sham Patent-Infringement Suits to Delay Generic Entry

124. In response to Allergan's Orange Book listings, and exactly as Allergan had planned, generic competitors provided paragraph IV certifications with respect to the Second Life Patents. Generic manufacturers Akorn, Mylan, Teva, Apotex, and Pfizer subsidiary Innopharma all submitted paragraph IV certifications within weeks of each other beginning in July 2015, asserting that the Second Life Patents were either invalid or non-infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate basis to enforce them. Yet Allergan responded to each of the above paragraph IV certifications by filing multiple patent infringement actions in the federal district court of the Eastern District of Texas, beginning on August 24, 2015 (the court later joined subsequent paragraph IV certificants (the "Infringement Action").

125. These infringement suits triggered the automatic 30-month stay of any FDA final approval of these ANDAs.

126. On October 16, 2017, after bench trial in August, the district court presiding over the Infringement Action found the Second Life Patents invalid based on obviousness. In a

thorough 135-page post-trial Findings of Fact and Conclusions of Law, the court found that Allergan had secured these Patents "by way of a presentation that was more advocacy than science." Invalidation Decision at 133. The court found particularly compelling the 2009 concessions, the fact that Allergan's "unexpected" results were foreseeable based on the early cyclosporine studies, and that in any event, the "new" Restasis formulation claimed by the Second Life Patents had statistically the same efficacy as one of the prior art examples in Ding I.

127. The court also dismissed other arguments Allergan made at trial, including assertions that the surprise results arose from a difference between the Phase 2 and 3 studies, and that there were objective, valid reasons for issuing new patents:

> While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [Second Life] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.

Id. at 134-35.

128. Allergan brought these infringement suits regardless of any objective merit. Indeed, Allergan conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the Second Life Patents) were obvious in light of Ding I, and Allergan knew it had obtained the Second Life Patents only through its fraudulent misrepresentations to the PTO. Accordingly, there never was any objective merit to any of these infringement suits.

129. The objective merits were irrelevant, however, to Allergan's true purpose. Allergan filed those suits not to vindicate a desire to protect legitimately secured patents but to improperly use government process and the workings of the Hatch-Waxman Amendments to delay generic competition to its Restasis monopoly. Indeed, Allergan's subjective intent in filing

these suits is evident from the complaint it filed. In its prayer for relief, Allergan demanded that the district court order, notwithstanding any lack of authority to do so, that "the effective date of any FDA approval" of any Restasis ANDA be "a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity" of the Second Life Patents. *See* Amended Complaint at 127, 129, 131, 132, *Allergan, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455 (E.D. Tex. Feb. 18, 2016), ECF No. 96. Essentially, Allergan was asking the court to insert itself into the FDA's ANDA review process to forestall competition.

130. Allergan knew that if it filed even the most baseless of patent infringement suits, it would still obtain and immediately benefit from the automatic 30-month stay of FDA final approval of any generic cyclosporine product. For a $1.5 billion a year franchise, every extra month Allergan could postpone competition from generic cyclosporine added another $125 million to its revenues.

F. Allergan Abuses the FDA's Citizen Petition Process to Delay Generic Entry

131. In early 2014, just as the PTO started issuing the Second Life Patents, Allergan started to bombard the FDA with groundless, repetitive, and serial petitions seeking to delay the FDA's approval of any Restasis ANDA.

132. On January 15, 2014, the day after Allergan listed the first of the Second Life Patents in the Orange Book, Allergan submitted a citizen petition relating to the FDA's non-binding June 2013 draft guidance that provided Restasis ANDA applicants with two options to demonstrate the bioequivalence necessary for ANDA approval. One of those options, the in vitro option, did not require the kind of very time-consuming and expensive in vivo clinical endpoint studies that brand manufacturers generally must undertake in support of the branded drug's NDA

(but that, due to their prohibitive expense, generic manufacturers ordinarily do not undertake in support of their ANDAs). Allergan then filed a superseding citizen petition on February 28, 2014. Allergan's citizen petition explicitly requested that the FDA "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence." Allergan Feb. 28, 2014 Citizen Petition at 1. Allergan made six sweeping requests, ranging from asking that the FDA withdraw the June 2013 guidance to listing various onerous conditions the FDA should require and/or undertake before approval of any Restasis ANDA. It based its requests on Section 505(q) of the FDCA, namely, it contended "a delay is necessary to protect the public health."

133. Allergan's views were not new to the FDA—the views expressed in its February 28, 2014 petition were entirely redundant to its comments on the draft guidance, which it had submitted on August 17, 2013. There, in a 43-page comment, Allergan argued that the FDA could not approve any Restasis ANDA that demonstrated bioequivalence through the in vitro option provided in the draft guidance and requested that the "FDA replace the Draft Guidance with a revised guidance document that explains in vivo comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to RESTASIS." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013.

134. In support of its February 2014 citizen petition Allergan also referenced the fact that "[n]umerous physicians submitted comments, drawn from their clinical experience, criticizing the draft guidance's in vitro approach," which Allergan dubbed "strikingly one-sided" in support of Allergan's position, but failed to disclose to the FDA its relationship to those commenting physicians. For example, Dr. Stephen Pflugfelder filed a comment on the draft

guidance posted on August 9, 2013, stating his concern that the FDA might "approve generic cyclosporine ophthalmic emulsions without human clinical trials." Neither Allergan nor Dr. Plugfelder disclosed Allergan paid him roughly $70,000 in 2013 for his "consulting" services and "travel and lodging," generally and specifically relating to Restasis.[6] Similarly, in a comment dated August 16, 2013, Dr. Jai G. Parekh claimed he was "surprised by the recent FDA-related issue on bioequivalence." Neither Allergan nor Dr. Parekh disclosed that Allergan paid him nearly $9,000 in 2013 for his services relating to Restasis and other drugs, $2,500 of which was explicitly relating to consulting on Restasis and paid to him five days after he submitted his comment.[7] Dr. Marc Bloomenstein's comment, posted August 15, 2013, raises a similar alarm, and similarly fails to disclose payments from Allergan. Dr. Bloomenstein's 144 payments from Allergan in 2013 amounted to $47,557, all but two of which explicitly related to Restasis.[8]

135. Regurgitating its views, and those of its paid consultants, in its February 2014 citizen petition, Allergan again urged the FDA, *inter alia*, not to approve any Restasis ANDAs not supported by in vivo clinical endpoint studies using human subjects, professing concern that "rushing prematurely to approve a proposed generic drug poses a risk to patient health and could weaken the public's trust in generic drugs as a class." Allergan Feb. 28, 2014 Citizen Petition at 4. But to its shareholders, Allergan cited its citizen petition submissions as an example of what it was doing in response to "intense competition from generic drug manufacturers." *See* Allergan, Inc., U.S. Securities and Exchange Commission Form 10-K for FY Ended 12-31-2014 at 12, 48.

137. In a November 20, 2014 letter, the FDA substantively rejected the six requests in

[6] *See* ProPublica, Dollars for Docs—Stephen C Pflugfelder, https://projects.propublica.org/docdollars/doctors/pid/356009 (last visited Jan.18, 2018).
[7] *See* ProPublica, Dollars for Docs—Dr. Jai Parekh, https://projects.propublica.org/docdollars/doctors/pid/37605 (last visited Jan. 18, 2018).
[8] *See* ProPublica, Dollars for Docs—Dr. Marc Bloomenstein, https://projects.propublica.org/docdollars/doctors/pid/25861 (last visited Jan. 18, 2018).

Allergan's citizen petition. The FDA granted Allergan's request only to the limited extent that Allergan requested notice and an opportunity to comment on the FDA's recommended bioequivalence methodology, and agreed to explain the scientific basis for allowing ANDA applications to rely solely on in vitro studies to show bioequivalence, all of which the FDA's denial of the citizen petition itself provided. The FDA's agreeing to allow comment was in no sense a "win" for Allergan, because the FDA's door is always open (it did not, for example, reject Allergan's unsolicited submission of a response to the FDA's "Dear ANDA Applicant" letter regarding the 180-day exclusivity period). Indeed, the FDA specifically refuted Allergan's argument that the FDA was legally required to use notice-and-comment rulemaking. Ltr. from J. Woodcock to D. Burrow Re: Docket No. FDA-2014-P-0304, at 27-29 (Nov. 20, 2014) ("None of your legal contentions has merit . . . .") Similarly, the FDA's response to Allergan's request for an explanation was no achievement of an end-goal for Allergan's advocacy. It was simply a delineation of why Allergan was wrong and why, therefore, the FDA rejected the petition in its entirety.

138. In its rejection of Allergan's substantive requests, the FDA explained the important policy goals underlying its reasoning:

> The Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data enables FDA to effectuate several long-recognized policies that protect the public health: (1) refraining from unnecessary human research when other methods of demonstrating bioequivalence meet the statutory and regulatory standards for approval; (2) permitting the Agency to use the latest scientific advances in approving drug products; (3) protecting the public by ensuring only safe effective generic drugs are approved for marketing; and (4) making more safe and effective generic drugs available.

Id. at 7-8 (citations omitted). The FDA then explained that for drugs that are primarily absorbed systemically, in vivo studies are often preferred, but that these studies are "usually of limited utility for locally acting, non-systemically absorbed drug products," like Restasis. *Id.* at 8. The

2013 draft guidance recommended either type of study, but noted that the "modest efficacy demonstrated by Restasis" meant that "a bioequivalence study with clinical endpoints … may not be feasible or reliable." *Id.* at 11.

139. The FDA's rejection of Allergan's arguments did not stop there. The agency observed that the kind of clinical endpoint study Allergan advocated should be the sole bioequivalency requirement for any Restasis ANDA approval "likely would not be as reliable at detecting differences in the formulation and manufacturing process of a proposed generic product when the [reference listed drug, *i.e.*, Restasis] shows only a modest clinical effect," particularly given "that such [clinical] trials may present economic and logistical changes for ANDA sponsors." *Id.* at 13. The agency further explained why the studies Allergan demanded "may be limited by confounding variables such as different severities of disease and variability in the definition of the instrument used to measure efficacy, among other issues." *Id.* at 12. It thus concluded that "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic cyclosporine. *Id.* at 13.

140. In rejecting Allergan's arguments, the FDA also considered confidential research Allergan had sent purporting to show that a test emulsion could satisfy the draft guidance's in vitro criteria but still demonstrate sufficient variability to make bioequivalence to Restasis in humans unlikely. *Id.* at 22. The FDA rejected this as a basis for altering its guidance because, among other reasons, it was "not clear that the emulsions that [Allergan] tested fully satisfied the draft guidance's in vitro criteria." *Id.*

141. Barely a month after the FDA's denial of this citizen petition, Allergan filed another on December 23, 2014. Allergan made much of the FDA's acknowledgment that it was

"considering revising" the draft guidance. But as the FDA explained, the fact that the agency was considering input in preparation for releasing final guidance did not mean that it would be unable to receive any Restasis ANDA for substantive review in the interim (*i.e.*, to make the threshold determination that the ANDA was sufficiently complete to permit substantive review), as Allergan would have it. The balance of Allergan's 51-page citizen petition essentially repeated the prior petition's arguments. Allergan made at least four supplements over the next several months, adding to its requests in an August 16, 2015 supplement, in which it again demanded to know which in vitro methods the FDA intended to apply or accept to determine bioequivalence for Restasis ANDAs. In addition, it requested that the FDA convene a committee of outside experts to evaluate the use of in vitro methods, and that the FDA refuse to receive, review, or approve any ANDAs until the requested evaluation was complete.

142. In the summer of 2015, Allergan also took the opportunity to petition the FDA in response to a "Dear ANDA Applicant" letter the FDA sent soliciting the views of all the ANDA filers. The FDA sought their positions on which ANDA applicant it should deem the first filer, thanks to the confusion Allergan's Orange Book listings had caused. Allergan, of course, was not an ANDA filer. It nonetheless took the opportunity to again advocate against the FDA's approval of any Restasis ANDA that was not supported by clinical end-point studies. Ltr. from D. Moxie to Division of Dockets Management (HFA-305), Food and Drug Administration, Re: Docket No. FDA-2015-N-2713—Abbreviated New Drug Applications for Cyclosporine Ophthalmic Emulsion, Sept. 28, 2015. Because, in its view, no ANDA applicant had submitted such clinical endpoint studies, no ANDA was complete and thus none could be first. The FDA has yet to publically opine on these Dear ANDA Applicant responses, Allergan's related petition, and the first-filer status issues.

143. On February 10, 2016, the FDA once again substantively denied Allergan's citizen petition, granting it only to the limited extent of providing its grounds for doing so—and indicating it had delayed any consideration of Restasis ANDA approval pending its consideration of Allergan's petition. The FDA noted that the December 2014 citizen petition "repeats many of the assertions that were at the center of Allergan's previous petition" and declined to repeat the FDA's answers. *See* Ltr. from J. Woodcock to D. Moxie & R. Bellantone re Docket Nos. FDA-2015-P-0065 and FDA-2015-P- 1404, Feb. 10, 2016, at 13. The FDA reminded Allergan that Allergan's "various claims and assertions . . . are premature" given the draft nature of the guidance. Although the FDA agreed to *permit* in vivo studies as part of an ANDA, it did not *require* one, as advocated by Allergan. Moreover, the FDA expressed continued doubts about such a study and revised its guidance to recommend that an ANDA applicant contemplating one submit the study protocol to the FDA for review. Elsewhere, the FDA noted that Allergan's claims, many of them repeated from the prior Petition, "[n]ot only . . . lack legal support, they also rest on flawed logic." *Id.* at 37.

144. Undeterred by their repeated rejection on the merits, Allergan continued pressing the same arguments, not only in further comments on the (still) draft guidance, *see, e.g.*, Allergan, Inc., Ltr. from D. Moxie to Division of Dockets Management, Food and Drug Administration re Docket No. FDA-2007-D-0369—Comments on October 2016 Draft Guidance on Cyclosporine, Dec. 5, 2016, but in yet another citizen petition, submitted on August 4, 2017. The petition predictably requested that the FDA refuse to accept or approve any pending ANDAs unless supported by in vivo clinical endpoint studies.

145. In its responses to date, the FDA denied every one of Allergan's lengthy serial petitions requesting FDA rejection of any Restasis ANDA absent supporting in vivo clinical

endpoint studies. *See* Ltr. from J. Woodcock to D. Moxie & R. Bellantone re Docket Nos. FDA-2015-P-0065 and FDA-2015-P- 1404, Feb. 10, 2016, at 30-40. But the FDA was obligated to respond fully to each of these citizen petitions, and those responses took time and resources.

146. As important, Allergan's petitions delayed ANDA approval. Indeed, in its February 2016 denial of Allergan's December 2014 citizen petition, the FDA expressly made clear that Allergan's serial petitioning claims were holding up the FDA's approval of any generic-cyclosporine ANDA. *See id.* at 44. In a November 2017 public workshop cosponsored by the FDA and the Federal Trade Commission, Prof. Michael Carrier, author of a leading treatise on antitrust and intellectual property, cited Allergan's citizen petitions as an example of using citizen petitions as a "bottleneck." He asserted that "generics Mylan, Teva, [and] Akorn still cannot enter market because of [Allergan's] Aug. 2017 petition."[9]

147. Allergan's serial petitioning actions thus delayed FDA approval of any Restasis ANDA, and continues to do so, just as Allergan intended.

G. Allergan Enters a Sham Agreement With the Tribe in a Naked Attempt to Avoid PTAB Invalidation of the Second Life Patents

148. Allergan's latest, concurrent effort to forestall competition in the market for cyclosporine stems from a series of IPR requests. In June 2015, Apotex, which subsequently provided Allergan notice of its Second Life Patent paragraph IV certifications on July 23, 2015, was the first ANDA applicant to petition the PTAB to initiate an IPR of the Second Life Patents. Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that the PTAB would invalidate the Second Life Patents. By that time, however, other ANDA applicants, including Mylan and Teva, had

[9] Michael A. Carrier, High Prices & No Excuse: 6 Anticompetitive Games, at 6, presentation at Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), available at https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

also petitioned the PTAB to institute IPR proceedings on the Second Life Patents. In December 2016, the PTAB resolved the very same question that the Allergan settlement with Apotex mooted the year before, concluding there was a reasonable likelihood that each of the Second Life Patents would be invalidated upon the PTAB's further review and thereby instituted proceedings against all six of the Second Life Patents.[10]

149. On September 8, 2017, Allergan entered into an agreement with the Tribe to convey ownership of the Second Life Patents with an exclusive license back to Allergan for "all FDA-approved uses in the United States" and a promise not to waive its sovereign immunity with respect to any IPR or other administrative action in the PTO related to the Patents. The Tribe did this in exchange for $13.75 million from Allergan, plus potentially $15 million in annual royalties. On September 22, after the Tribe and Allergan agreed to this sham transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity.

150. No objectively reasonable litigant could expect these shenanigans before the PTAB to succeed. Multiple cases have rejected similar schemes to game the law, including in the context of sovereign tribes where the only interest the tribe had was in being paid for the cover of immunity. *See People ex rel. Owen v. Miami Nation Enters.*, 386 P.3d 357 (Cal. 2016). The district court that issued the Invalidation Decision in the Infringement Action agreed to join the Tribe as a co-plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. The court explained that despite its "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed," it would "adopt the safer course of

[10] Because the terms of Allergan's settlement with Apotex in December 2015 (that avoided for as much as a year any risk that any of the Second Life Patents would be invalidated) were not public, Plaintiffs are not able, at present, to determine the extent to which that settlement may have violated the antitrust laws and other laws, and thus constitutes yet another component in Allergan's overall scheme.

joining the Tribe as a co- plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented." Mem. Op. & Order at 4, 9, *Allergan, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455 (E.D. Tex. Oct. 16, 2017), ECF No. 522.

151. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan's chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid "double jeopardy," that is, to disrupt adjudicative proceedings in one of two venues, even though Allergan itself had initiated proceedings in the other and could voluntarily dismiss the Texas action at any time.

152. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry, and in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry.[11] Licensing the Second Life Patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had prior to September 2017, and, from the Tribe's comments, was not made pursuant to a natural future interest either. Nor was the Tribe acting in its sovereign capacity—*e.g.*, regulating the sale or use of cyclosporine on a reservation—in entering its agreement with Allergan.

VIII. MARKET DEFINITION

153. The relevant geographic market is the United States and its territories and possessions.

154. To the extent Plaintiffs are legally required to prove monopoly power through

[11] *See* Saint Regis Mohawk Tribe—Office of Technology and Research, Frequently Asked Questions about New Research and Technology (Patent) Business, at 1 ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date."), *available at* https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf.

circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant product market is Restasis in all its dosage strengths, and its AB-rated generic equivalents. During the period relevant to this case, Allergan has been able to profitably maintain the price of cyclosporine ophthalmic emulsion well above competitive levels.

155. At all relevant times, Allergan's share of the relevant product and geographic markets was and remains 100%.

156. At all relevant times, Allergan had monopoly (market) power in the relevant product and geographic markets because it had and continues to have the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other products prescribed or used for the same purposes as Restasis. Allergan's power in the market for the sale of all cyclosporine ophthalmic emulsion products can be demonstrated with direct evidence.

157. Allergan has enjoyed monopoly power conferred by the Ding I patent since 1995, and since 2003, when it launched Restasis pursuant to FDA approval, Allergan has reaped significant commercial benefits. When it received FDA approval in December 2002, Allergan touted Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In its numerous filings with the FDA, Allergan has similarly touted the uniqueness of Restasis: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." Allergan, Inc., Citizen Petition, Feb. 28, 2014, at 13.

158. Manufacturers attempt to differentiate brand name drugs like Restasis based on

features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Restasis. This is in part because insurance bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Restasis.

159. Other products are not practical substitutes for cyclosporine. Artificial tears offer only ephemeral relief and do nothing to address the underlying causes of dry eye. Corticosteroids can address the inflammation associated with dry eye, but have unwanted side effects, as do devices like "punctal plugs," which block the tear ducts and help the eye retain naturally produced tears for longer. Patients treated with cyclosporine would not switch to these products in response to a small but significant nontransitory increase in the price of cyclosporine in sufficient numbers to make such a price increase by a hypothetical monopolist unprofitable. Shire US, Inc.'s 2016 introduction of its rival dry-eye disease product, Xiidra, has not resulted in lower Restasis prices, thus confirming Allergan's continued market power over the relevant cyclosporine market.[12]

160. Allergan's ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates lack of substitutability between Restasis and other drug products.[13] Restasis does not exhibit significant, positive cross-elasticity of demand with respect to price with any other DED medication. Other various DED treatments may exist, but none

[12] Allergan may also be improperly using its monopoly power in the cyclosporine market to unlawfully restrain Xiidra sales. In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an "ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan." Compl. at 1, *Shire US, Inc. v. Allergan, Inc.*, No. 2:17-cv-07716 (D.N.J. Oct. 2, 2017), ECF No. 1.

[13] *See* David Crow, *Allergan deal with Mohawk tribe casts patent shadow*, Fin. Times, Sept. 27, 2017 ("The average wholesale price of a 30-dose pack of Restasis has more than doubled from $117 in 2008 to almost $280 today….").

exhibits cross price elasticity with and therefore does not constrain the price of Restasis. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives, to the extent they exist, are not the same as economic alternatives.

161. Functional similarities between Restasis and other DED medications are insufficient to permit inclusion of those other molecules in the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. No other DED medication will take away sales of Restasis sufficient to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

162. Restasis is also not reasonably interchangeable with any products other than generic versions of Restasis that, if approved and rated as "AB" generic equivalents by the FDA, would compete in the cyclosporine market, because Restasis has significantly differentiating attributes making it a unique drug product. The FDA does not consider Restasis interchangeable with any similar medication. Nor does Allergan. For example, Restasis is a topical ophthalmic formulation, and as Allergan has explained, "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

163. Allergan needed to control only Restasis, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain its current prices of Restasis without losing substantial sales.

164. Allergan sold and continues to sell Restasis at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

165. Allergan exercised and continues to exercise its power to exclude and restrict competition to Restasis and its AB-rated equivalents.

166. Allergan, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of cyclosporine ophthalmic emulsion due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and high costs of entry and expansion.

IX. MARKET EFFECTS AND CLASS DAMAGES

167. To date, no generic manufacturer has entered the market with a generic cyclosporine ophthalmic emulsion product. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic cyclosporine ophthalmic emulsion products starting as early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its monopoly power in the market for cyclosporine ophthalmic emulsion through a scheme to exclude competition. The scheme forestalled generic competition and carried out its anticompetitive effect of maintaining supracompetitive prices for Restasis.

168. Allergan implemented its scheme by fraudulently obtaining the Second Life

Patents, wrongfully and knowingly submitting these invalid patents for listing in the Orange Book, prosecuting sham patent infringement lawsuits against the would-be generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and entering into an anticompetitive agreement with the Tribe in a blatant attempt to insulate the Second Life Patents from invalidation in the PTAB IPR proceedings. These acts, individually and in combination, were anticompetitive.

169. If Allergan had not defrauded the PTO, the Second Life Patents would never have been issued, and Allergan could not have listed them in the Orange Book or used them as a vehicle to bring sham suits against would-be makers of generic cyclosporine ophthalmic emulsion products, the filing of which automatically stayed any FDA final approvals of all would-be generic alternatives. AB-rated generic Restasis manufacturers would have been able to launch generic cyclosporine ophthalmic emulsion products by May 17, 2014.

170. Allergan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis from generic competition. Allergan's actions allowed it to maintain a monopoly and exclude competition in the market for cyclosporine ophthalmic emulsion products, *i.e.*, Restasis and its AB-rated generic equivalents.

171. Allergan's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Restasis without generic competition. But for the illegal conduct of Allergan, one or more of the ANDA filers would have begun marking generic versions of Restasis at least as early as May 17, 2014.

172. The generic manufacturers seeking to sell generic cyclosporine have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs,

marketing generic pharmaceutical products, and manufacturing commercial-launch quantities adequate to meet market demand, and at least several of these generic manufacturers would have been ready, willing, and able to launch its generic version of Restasis by May 17, 2014 were it not for Allergan's unlawful acts.

173. Allergan's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any generic version of Restasis, has caused and will cause Plaintiffs and the Classes to pay more than they would have paid for cyclosporine, absent Allergan's unlawful conduct.

174. Typically, generic versions of branded drugs are initially priced significantly below the corresponding reference listed drug branded counterpart as to which they are AB-rated. As a result, upon generic entry, indirect purchasers' purchases of branded drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generic versions of the drug.

175. This price competition enables all purchasers of the drug to (a) purchase generic equivalents of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the branded drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

176. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Allergan, indirect purchasers, such as Plaintiffs and members

of the Classes, would have paid less for cyclosporine ophthalmic emulsion by (a) substituting purchases of less expensive AB-rated generic Restasis for their purchases of more-expensive branded Restasis, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c) purchasing cyclosporine ophthalmic emulsion at lower prices sooner.

177. Allergan's unlawful conduct had substantial and significant intrastate effects in each state because, *inter alia*, Restasis was sold to consumers and third-party payors in each state at higher prices than would have existed absent the unlawful conduct, and Allergan entered into an unlawful agreement that affected commerce, product availability, and competition in each state.

178. Thus, Allergan's unlawful conduct deprived Plaintiffs and the Classes of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT AND INTERSTATE COMMERCE

179. During the relevant period, Plaintiffs and members of the Classes purchased substantial amounts of Restasis indirectly from Allergan. As a result of Allergan's unlawful anticompetitive conduct, members of the Classes were compelled to pay, and did pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were substantially greater than the prices that members of the Classes would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Restasis was artificially inflated by Allergan's illegal conduct, and (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

180. As a consequence, Plaintiffs and members of the Classes have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon

proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the overcharge passed through the chain of distribution to end payors such as Plaintiffs and members of the Classes.

181. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

182. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Restasis to Plaintiffs and the Classes.

183. Allergan's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions.

184. The prices were inflated as a direct and foreseeable result of Allergan's anticompetitive conduct.

185. The inflated prices the Classes paid are traceable to, and the foreseeable result of, Allergan's overcharges.

186. Allergan's efforts to monopolize and restrain competition in the market for cyclosporine have substantially affected interstate commerce.

187. At all material times, Allergan manufactured, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state lines and throughout the United States.

188. At all material times, Allergan transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of Restasis.

189. In furtherance of its efforts to monopolize and restrain competition in the market for cyclosporine, Allergan employed the United States mails and interstate telephone lines, as well as means of interstate travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

CLAIMS FOR RELIEF

190. With respect to each of the claims asserted in Counts One through Four:

a. Plaintiffs and members of the Nationwide Injunctive Relief Class have been injured in their business or property by Allergan's antitrust violations. Their injury consists of having paid higher prices for their cyclosporine requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent and flows from that which makes Allergan's conduct unlawful. Plaintiffs and members of the Nationwide Injunctive Relief Class also intend to purchase cyclosporine in the future and will continue to be injured unless the alleged conduct is enjoined. Accordingly, Plaintiffs and the Nationwide Injunctive Relief Class are the proper entities to bring a case concerning Allergan's alleged conduct.

b. Allergan's anticompetitive conduct as alleged herein is not protected by the *Noerr-Pennington* or state action doctrines.

c. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

d. Allergan's unlawful conduct is continuing and will continue unless enjoined by this Court.

e. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, Plaintiffs and the Nationwide Injunctive Relief Class seek the issuance of an injunction against Allergan, preventing and restraining the violations alleged herein.

COUNT ONE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT
MONOPOLIZATION THROUGH WALKER PROCESS FRAUD

191. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

192. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

193. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by wrongfully asserting patents obtained by fraud to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

194. Allergan knowingly and intentionally asserted the invalid Second Life Patents in

order to maintain its monopoly power. This was intended to, and in fact had the effect of, blocking and delaying entry of AB-rated generic versions of Restasis.

195. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability—including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar—made misrepresentations of fact to the PTO. These included:

> • Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Teat Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the … formulation discussed in Example 1E of Ding, tested in Phase 2 trials…. This was clearly a very surprising and unexpected result."
>
> • Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staningin score in both of the Phase 3 studies compared to the … formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result."
>
> • Figures 1-4 in Dr. Schiffman's declaration reported figures from the Sall paper but omitted all error bars and p-values. In truth, as the court in the Infringement Action later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high.[14] The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance.
>
> • Dr. Schiffman did not disclose to the PTO that he was comparing different Schirmer tear test scores—one without anesthesia in Phase 2 and one with anesthesia in Phase 3—in order to purportedly show a difference in efficacy. As the court in the Infringement Action later found, only the Schirmer tear test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation. "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation' was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper.
>
> • Dr. Schiffman did not disclose to the PTO that the method he chose to calculate the differences in efficacy "exaggerated the difference in the raw values between the two."[15]

[14] Invalidation Decision at 76.
[15] *Id*. at 78.

• The calculations in Dr. Schiffman's table are misleading:

p. Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results;

q. Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant; and

r. Dr. Schiffman only included data from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the second wave formulation.

• Dr. Schiffman did not tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was "unexpected" as of the Restasis patent's priority date.

196. These representations were material. The examiner had repeatedly rejected the applications as obvious before Allergan's misleading statements and omissions. The examiner had also earlier rebuffed Allergan's purported secondary considerations of non-obviousness (including commercial success and unmet need). The PTAB's later decision, as well as the court's subsequent decision in the Infringement Action, support the materiality of these misrepresentations and omissions.

197. Allergan made these statements with intent to deceive the PTO. The misleading statements were made intentionally, not accidentally. Allergan was motivated to obtain a longer period of patent protection, given the large sales of Restasis and the importance of the product to the company. The misleading statements were made only after the examiner rejected the application (not with the initial filing) and were made to overcome a rejection and support patentability. There is no innocent explanation for presenting the information as it was presented in the misleading declaration and accompanying submissions; the only reasonable inference is

that Allergan intended to deceive the PTO.

198. The PTO reasonably relied on Allergan's false and misleading statements in issuing the Second Life Patents. The examiner stated that the Schiffman declaration was deemed sufficient to overcome his earlier rejection based on Ding I because "Examiner is persuaded that, unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I." The Examiner also explained that the declarations "illustrate that the claimed formulations . . . also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4- fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compare to the . . . formulation tested in Phase 2 and disclosed in Ding."

199. But for Allergan's misrepresentations and omissions, the Second Life Patents would not have issued. Had they not issued, there would have been no patent-based impediment to generic versions of Restasis entering the market from May 17, 2014 onwards.

200. Allergan listed the Second Life Patents in the Orange Book and later asserted them against all would-be generic competitors.

201. But for Allergan's asserting the fraudulently obtained patent, generic versions of Restasis would have been available as early as May 17, 2014, and in any case within the Class Period.

202. Through this conduct, Allergan intentionally and wrongfully maintained monopoly power with respect to cyclosporine in violation of Section 2 of the Sherman Act. 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Nationwide Injunctive Relief Class have been injured in their business and property and

are threatened with future injury in the form of paying artificially inflated prices for cyclosporine ophthalmic emulsion products.

COUNT TWO
VIOLATION OF SECTION 2 OF THE SHERMAN ACT
MONOPOLIZATION THROUGH OVERARCHING ANTICOMPETITIVE SCHEME

203. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

204. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

205. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

206. Allergan knowingly and intentionally engaged in an anticompetitive scheme in order to maintain its monopoly power, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Restasis. This scheme included:

- Prosecuting serial baseless patent applications and ultimately obtaining the Second Life Patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;

- Improperly listing the Second Life Patents in the Orange Book;

- Engaging in multiple sham litigations;

• Submitting serial sham citizen petitions; and

• Entering into a sham transfer and licensing agreement with the Tribe and abusing the PTAB's *inter partes* review process through sham transfer of the Second Life Patents.

207. By means of this scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to Restasis in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Nationwide Injunctive Relief Class paid artificially inflated prices for their cyclosporine ophthalmic emulsion requirements.

208. Allergan knowingly and intentionally committed *Walker Process* fraud to induce the PTO to grant the Second Life Patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted false sworn declarations in 2013, which Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by prior art (*i.e.*, Ding I), when in fact the data presented was neither new nor surprising. Had Allergan made clear to the PTO examiner that the 2013 declarations statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan's Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the Second Life Patents.

209. Allergan knew when it listed the Second Life Patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the Second Life Patents should not have been listed in the Orange Book. Allergan knew that listing the Second Life Patents in

the Orange Book would force ANDA applicants to file paragraph IV certifications that would provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, could trigger an automatic stay of any FDA final approval of any new paragraph IV-certified ANDA applicant's generic Restasis product for a period of up to 30 months.

210. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis. Allergan intentionally and deceptively alleged the generic manufacturers' products infringed the Second Life Patents, knowing when those suits were filed that such patents were wrongfully obtained though fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently obtained and otherwise invalid Second Life Patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed this sham lawsuit for the purposes of using a governmental process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly power over Restasis, regardless of any actual merit to its infringement claims.

211. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA, the purpose and intent to which was delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition.

212. Allergan knowingly and intentionally transferred the Second Life Patents to the

Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands located in New York—in an attempt to evade invalidation of those patents and cessation of its Restasis monopoly, which illustrates the extraordinary measures Allergan was willing to take in its stop-at-nothing desperation to delay competition.

213. By means of the overarching anticompetitive scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to cyclosporine in violation of Section 2 of the Sherman Act. 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Nationwide Injunctive Relief Class have been injured in their business and property and are threatened with future injury in the form of paying artificially inflated prices for cyclosporine ophthalmic emulsion products.

COUNT THREE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT
AGREEMENT IN RESTRAINT OF TRADE

214. Plaintiffs repeat and incorporate by reference all of the preceding paragraphs and allegations.

215. Allergan's anticompetitive ownership transfer and licensing Agreement with the Tribe as set forth in this Complaint has violated Section 1 of the Sherman Act. 15 U.S.C. § 1.

216. Allergan and the Tribe are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from the Agreement, Allergan and the Tribe are economically independent from each other.

217. Allergan and the Tribe have acted in concert during the proceedings before the PTAB.

218. Allergan and the Tribe entered their conspiracy with the purpose and effect of

restraining competition in the relevant market.

219. During the Class Period, Allergan had significant pricing (*i.e.*, market) power in the market for cyclosporine. The Tribe was only a participant in this market insofar as Allergan could use it as a conduit to protect Allergan's market share through baseless assertions of sovereign immunity.

220. Allergan and the Tribe's conspiracy had no procompetitive benefits; it did nothing to increase competition in the market for cyclosporine. It instead inflicted substantial competitive harms, namely by preventing entry by generics and raising the price of Restasis beginning no later than September 8, 2017.

221. Allergan and the Tribe affected interstate commerce by keeping the price of Restasis unreasonably high due to their wrongful restraint of trade.

222. As a direct and proximate result of Allergan and the Tribe's conspiracy, Plaintiffs and members of the Nationwide Injunctive Relief Class have been injured in their business and property and are threatened with future injury in the form of paying artificially inflated prices for cyclosporine ophthalmic emulsion products.

COUNT FOUR
VIOLATION OF SECTION 2 OF THE SHERMAN ACT
CONSPIRACY TO MONOPOLIZE

223. Plaintiffs repeat and incorporate by reference all by reference all of the preceding paragraphs and allegations.

224. Allergan conspired with the Tribe, through their anticompetitive ownership transfer and licensing Agreement, to monopolize the market for cyclosporine in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

225. Allergan and the Tribe are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from the Agreement, Allergan and the Tribe are economically

independent from each other.

226. Allergan had a specific intent to monopolize. Allergan specifically intended to use the Agreement to invoke the Tribe's sovereign immunity to protect the Second Life Patents before the PTAB in its *inter partes* reviews. Protecting Allergan's invalid and fraudulently obtained patents in the IPR process has already further delayed generic entry into the relevant market.

227. As a direct and proximate result of Allergan's and the Tribe's conspiracy, Plaintiffs and members of the Nationwide Injunctive Relief Class have been injured in their business and property and are threatened with future injury in the form of paying artificially inflated prices for cyclosporine ophthalmic emulsion products.

COUNT FIVE
VIOLATION OF STATE ANTITRUST LAWS
(ON BEHALF OF PLAINTIFFS AND THE DAMAGES CLASS)

228. Every paragraph above and in the following counts is incorporated herein by reference.

229. At all relevant times, Allergan possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Allergan possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

230. Through each of the alleged actions individually—including but not limited to its *Walker Process* fraud and conspiracy with the Tribe—and through its overarching anticompetitive scheme, as alleged extensively above, Allergan willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured competition, Plaintiffs, and the Classes.

231. Plaintiffs and members of the Damages Class have been injured in their business or property by Allergan's antitrust violations. Their injury consists of having paid higher prices

for their cyclosporine ophthalmic emulsion requirements than they would have paid in the absence of those violations.

232. It was Allergan's conscious objective to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

233. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

234. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Damages Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq.*, with respect to purchases in California by members of the Damages Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Damages Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class, and such conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Haw. Rev. Stat. §§ 480, *et seq.*, with respect to purchases in Hawaii by members of the Damages Class.

f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois by members of the Damages Class.

g. Iowa Code § 553.5, *et seq.*, with respect to purchases in Iowa by members of the Damages Class.

h. Kan. Stat. Ann. § 50-101, *et seq.*, with respect to purchases in Kansas by members of the Damages Class.

i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class in actions and transactions occurring primarily and substantially within Massachusetts.

j. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Damages Class.

k. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Damages Class.

l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class.

n. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Damages Class.

o. Mont. Code Ann. §§ 30-14-101, *et seq.*, with respect to purchases in Montana by members of the Damages Class.

p. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class.

q. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases in New Hampshire by members of the Damages Class.

r. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Damages Class.

s. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class.

t. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases in New York by members of the Damages Class, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York Class members to recover by way of a class action.

u. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class.

v. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Damages Class.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Damages Class.

x. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class.

y. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South

Dakota by members of the Damages Class.

z. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Damages Class. Members of the Damages Class include citizens or residents of Utah.

bb. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Damages Class.

cc. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class.

dd. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Damages Class.

235. Plaintiffs and members of the Damages Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Count. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above jurisdictions were designed to prevent, and flow from that which makes Allergan's conduct unlawful.

236. Plaintiffs and the Damages Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT SIX
VIOLATION OF STATE CONSUMER PROTECTION STATUTES
(ON BEHALF OF THE PLAINTIFFS AND THE DAMAGES CLASS)

237. Plaintiffs incorporate by reference the allegations set forth above as if fully set forth herein.

238. Allergan engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection and unfair competition statutes listed below.

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by members of the Damages Class.

b. Ariz. Rev. Stat. §§ 44-1521, *et seq.*, with respect to purchases in Arizona by members of the Damages Class.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases in the District of Columbia by members of the Damages Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class.

f. Haw. Rev. Stat. §§ 480, *et seq.*, with respect to the purchases in Hawaii by members of the Damages Class.

g. Kan. Stat. §§ 50-623, *et seq.*, with respect to the purchases in Kansas by members of the Damages Class.

h. Idaho Code §§ 48-601, *et seq.*, with respect to the purchases in Idaho by members of the Damages Class.

i. 815 ILCS §§ 505/1, *et seq.*, with respect to the purchases in Illinois by members of the Damages Class.

j. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases in Maine by members of the Damages Class.

k. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class.

l. Mich. Comp. Laws Ann. §§ 445.901, *et seq.*, with respect to purchases in Michigan by members of the Damages Class.

m. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class.

n. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by members of the Damages Class.

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases in Montana by members of the Damages Class.

p. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class.

q. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in Nevada by members of the Damages Class.

r. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire by members of the Damages Class.

s. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class.

t. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by members of the Damages Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class.

v. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases in Oregon by members of the Damages Class.

w. 73 Pa. Con. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in Pennsylvania by members of the Damages Class.

x. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class.

y. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases in South Dakota by members of the Damages Class.

z. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class.

aa. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases in Utah by member of the Damages Class.

bb. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases in Virginia by members of the Damages Class.

cc. Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by member of the Damages Class.

dd. West Virginia Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class.

239. As a direct and proximate result of Allergan's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of Restasis and forced to pay higher prices.

240. There was and is a gross disparity between the price that Plaintiffs and the Class members paid for the brand Restasis product and the value received, given that a much cheaper substitute generic product should have been available sooner and in greater quantity, and prices for brand Restasis should have been much lower, but for Allergan's unlawful conduct.

241. Plaintiffs and members of the proposed Damages Class have been injured in their business and property by reason of Allergan's anticompetitive, unfair, or deceptive acts alleged in detail above. Their injury consists of paying higher prices for Restasis than they would have paid in the absence of these violations, and being denied the opportunity to purchase the cheaper generic Restasis. These injuries are of the type the state consumer protection and unfair business practices statutes were designed to prevent and directly result from Allergan's unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Classes, pray that the Court:

1. Determine that this Action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this Action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare Plaintiffs as named representatives of the Classes;

2. Enter judgment against Defendant and in favor of Plaintiffs and the Classes;

3. Enjoin Allergan from continuing the illegal activities alleged herein;

4. Award the Damages Class treble damages, plus interest, in accordance with law;

5. Award Plaintiffs and the Classes their costs of suit, including reasonable

attorneys' fees as provided by law; and

6. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by Allergan's unlawful conduct, as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the proposed Classes, demand a trial by jury on all issues so triable.

Dated: February 6, 2018

/s/ Bethany R. Turke

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